

REMARKS

Claims 13, 14, 16, and 17 are pending and under examination. Applicants have amended claims 16 and 17 to recite the step of "detecting accelerated salivation in the subject." The specification supports this amendment at, for example, Experiment 2 (page 19, line 13 to page 20, line 17), Experiment 3 (page 20, line 19 to page 23, line 24), and Experiment 4 (page 24, line 1 to page 25, line 21). Thus, this amendment does not introduce new matter.

Interview Summary

Applicants wish to thank Examiner Pagonakis and Examiner Fetterolf for the interview held on June 17, 2010, with Applicants' representatives. Applicants agree with the Examiner's Interview Summary mailed June 21, 2010, except that the pending rejection under § 102(b) was discussed, not an obviousness rejection under § 103(a). The substance of this interview is also contained in the remarks below.

Rejection Under 35 U.S.C. § 102

The Office continues to reject claims 13, 14, 16, and 17 under 35 U.S.C. § 102(b) as allegedly anticipated by Urashima as evidenced by Fox et al. (Sem. in Arthritis & Rheumatism, 14(2):77-105, November 1984) ("Fox"). See Office Action, page 2. According to the Office, Urashima "teaches the treatment of Sjogren's syndrome and 'dry eye' syndrome with administration of the elected compound." *Id.* The Office further contends that "Fox et al. teach that Sjogren syndrome is an autoimmune condition in which dry eyes (karatoconjunctivitis sicca) and dry mouth (xerostomia) result from lymphocytic infiltration of lacrimal and salivary glands." *Id.* at page 3.

Acknowledging that "Urashima et al is silent as to the effect of the elected compound to accelerate salivation," the Office nonetheless contends that the "the administration of the claimed compound to patients suffering from Sjogren's syndrome is expected to necessarily have the claimed effect on acceleration of salivation." *Id.* While acknowledging that the Declaration of Dr. Hisashi Nagamoto "allegedly demonstrate[s] that oral administration of the elected carbostyryl compound does not successfully treat dry eye," the Office contends that "Urashima et al. and the instant claims are drawn to the administration of rebamipide to those suffering from Sjogren's syndrome." *Id.* The Office alleges that "[t]hough acceleration of salivation itself was not recognized as a pharmacological effect of administering the elected compound, such an effect [is] would have necessarily occurred with administration of the elected compound to identical patient populations (i.e. Sjogren's syndrome patients)." *Id.* at page 3-4.

In order to anticipate a claim, a reference must either expressly or inherently disclose each and every element of that claim. See MPEP § 2131. Applicants do not agree that Urashima anticipates the pending claims for at least the reasons set forth in the Reply filed October 15, 2009. Solely to advance prosecution and without acquiescing to the rejection, however, Applicants have amended claims 16 and 17 to further recite the step of "detecting accelerated salivation in the subject." Urashima focuses on the treatment of dry eye and therefore does not teach a method step involving detecting accelerated salivation. Because Urashima does not teach each and every element of independent claims 16 and 17, this reference cannot anticipate claims 13, 14, 16, and 17. Applicants therefore request that the Office withdraw this rejection.

Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of the application and the timely allowance of claims 13, 14, 16, and 17.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 19, 2010

By: 

Jared Schuettenhelm
Reg. No. 59,539
(650) 849-6752